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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/593,357	09/18/2006	Stefan Verseck	009848-0356700	8910
27500	7590	01/11/2010	EXAMINER	
PILLSBURY WINTHROP SHAW PITTMAN LLP			STRZELECKA, TERESA E	
ATTENTION: DOCKETING DEPARTMENT				
P.O BOX 10500			ART UNIT	PAPER NUMBER
McLean, VA 22102			1637	
			MAIL DATE	DELIVERY MODE
			01/11/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	10/593,357	VERSECK ET AL.
	<b>Examiner</b>	<b>Art Unit</b>
	TERESA E. STRZELECKA	1637

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 17 September 2009 and 07 December 2009.
- 2a) This action is **FINAL**.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) 1-5,7,8,10 and 11 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 6,9 and 12-15 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                         | Paper No(s)/Mail Date. _____ .                                    |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ . | 5) <input type="checkbox"/> Notice of Informal Patent Application |
|  | 6) <input type="checkbox"/> Other: _____ .                        |

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Applicant's election of SEQ ID NO: 72 and 84 in the reply filed on September 17, 2009 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).
2. The response was considered incomplete, as Applicants did not elect a SEQ ID NO for the  $\alpha$ -subunit. Mr. Robert Bedgood informed examiner in a telephone message on December 7, 2009, that SEQ ID NO: 50 was intended to be elected for the  $\alpha$ -subunit. Consequently, all three SEQ ID NOs were searched.
3. Claims 1-11 were previously pending, with claims 1-5, 7, 8, 10 and 11 withdrawn from consideration. Applicants amended claims 6 and 9 and added new claims 12-15. Claims 6, 9 and 12-15 will be examined to the extent that they read on SEQ ID NO: 50, 72 and 84.
4. Applicants' amendments overcame all of the previously presented rejections. This office action contains new grounds for rejection necessitated by amendment.

### ***Claim Rejections - 35 USC § 101***

5. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

6. Claims 6, 9 and 12-15 are rejected under 35 U.S.C. 101 because the claimed invention lacks patentable utility.

The pending claims have been reviewed in light of the Utility Examination Guidelines and Guidelines for Examination of Patent Applications under 35 U.S.C. 112, first paragraph,

A Written Description Requirement, Federal Register, Vol. 66, No. 4, pages 1092-1111, Friday, January 5, 2001.

The examiner is using the following definitions in evaluating the claims for utility.

"Specific" - A utility that is *specific* to the subject matter claimed. This contrasts with a *general* utility that would be applicable to the broad class of the invention.

"Substantial" - A utility that defines a "real world" use. Utilities that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use are not substantial utilities.

"Credible" - Credibility is assessed from the perspective of one of ordinary skill in the art in view of the disclosure and any other evidence of record that is probative of the applicant's assertions. That is, the assertion is an inherently unbelievable undertaking or involves implausible scientific principles.

"Well-established" - a specific, substantial, and credible utility which is well known, immediately apparent, or implied by the specification's disclosure of the properties of a material, alone or taken with the knowledge of one skilled in the art.

The current claims are drawn to a protein sequence comprising SEQ ID NO: 50, SEQ ID NO: 72 or SEQ ID NO: 50, 72 and 84 or sequences 90% identical to these SEQ ID NOS, where the protein has nitrile hydratase activity.

### **Credible Utility**

Following the requirements of the Utility Guidelines (See: Federal Register: December 21, 1999 (Volume 64, Number 244), revised guidelines for Utility.), the first inquiry is whether a credible utility is cited in the specification for use of the proteins. The only cited utility

identified by the examiner is the use of these proteins as nitrile hydratases. This utility is credible.

Upon identification of credible utilities, the next issue is whether there are any well established utilities for the protein. No well established utilities for the claimed protein are identified in the specification.

### **Substantial Utility**

Given the absence of a well established utility, the next issue is whether substantial utilities are disclosed in the specification. The following evidence is presented by Applicants in the specification: amino acid sequences with SEQ ID NO: 50 and 72, which are allegedly  $\alpha$ - and  $\beta$ -subunits of nitrile hydratases, were obtained by PCR amplification from metagenome libraries and cloning of the amplified fragments, the clones subsequently screened for nitrite hydratase activity (pages 21-26 of the specification). Only the following combination of subunits were shown to possess nitrile hydratase activity: SEQ ID NO: 49/71 (+ SEQ ID NO: 83), SEQ ID NO: 39/63; SEQ ID NO: 57/79 (+ SEQ ID NO: 85) and SEQ ID NO: 59/63 (page 24-26). There is no evidence that the combination of SEQ ID NO: 50 and 72 (with or without SEQ ID NO: 84) has nitrile hydratase activity.

Therefore a protein comprising SEQ ID NO: 50 and 72 lacks substantial utility, since further experimentation would be necessary to establish such a utility, i.e., the protein's function.

### **Specific Utility**

In view of the above, the combination of SEQ ID NO: 50 and 72 also lacks any specific utility.

Applicant should explicitly identify a specific and substantial utility for the claimed invention and establish a probative relation between any evidence of record and the originally disclosed properties of the claimed invention.

7. Claims 6, 9 and 12-15 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by a specific, substantial or a well-established utility for the reasons set forth above, one skilled in the art would not know how to use the claimed invention.

***Claim Rejections - 35 USC § 112***

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 6, 9 and 12-15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The current claims are drawn to a protein sequence comprising SEQ ID NO: 50, SEQ ID NO: 72 or SEQ ID NO: 50, 72 and 84 or sequences 90% identical to these SEQ ID NOs, where the protein has nitrile hydratase activity. However, Applicants did not show any evidence that a protein comprising the subunits with SEQ ID NO: 50 and 72, with or without SEQ ID NO: 84, possesses nitrile hydratase activity. Only the following combination of subunits were shown to

possess nitrile hydratase activity: SEQ ID NO: 49/71 (+ SEQ ID NO: 83), SEQ ID NO: 39/63; SEQ ID NO: 57/79 (+ SEQ ID NO: 85) and SEQ ID NO: 59/63 (page 24-26).

Therefore, Applicants were not in possession of the claimed invention.

10. No references were found teaching or suggesting claims 6, 9 and 12-15, but they are rejected for reasons given above.

*Conclusion*

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TERESA E. STRZELECKA whose telephone number is (571)272-0789. The examiner can normally be reached on M-F (8:30-5:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Teresa E Strzelecka  
Primary Examiner  
Art Unit 1637

/Teresa E Strzelecka/  
Primary Examiner, Art Unit 1637  
December 28, 2009